Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed Electrophysiology Catheter Cables

Reprocessed Device for Single Use

- **STERILE**

Explanation of Symbols

℞Only	Federal Law in the USA restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Catalogue Number
2	Do Not Reuse
	See Instructions For Use
	Do Not Use if Package is Damaged
	Keep Product Dry
	Keep Away from Sunlight

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Reprocessed Electrophysiology Catheter Cables

Electrophysiology Catheter Cable Description
Electrophysiology catheter cables are designed as electrode cables with a multi-pin connector on the distal end and the appropriate number of tails on the proximal end. The cables either interface an EP catheter with the appropriate external stimulation or recording equipment or, serve as an extension cable between an EP catheter and equipment out of immediate reach.

Indications for Use
Reprocessed electrophysiology catheter cables are indicated for use with the appropriate electrode catheter during electrophysiology studies.

Contraindications for Use
None

Warnings
- The use of this device requires a thorough understanding of the techniques and principles of angiography, electrophysiology and transvenous intracardiac electrophysiology studies and temporary pacing.
- Do not connect the electrophysiology catheter cable to devices or power sources other than the appropriate electrode catheter(s) and equipment. Connecting the electrophysiology catheter cable to an inappropriate electrical connection such as a wall socket may result in serious injury to patient and operator or damage to equipment.
- Employ proper electromechanical device guidelines and hospital standards in cases where conventional line powered equipment is used near the patient. Extraneous electrical currents may reach the electrophysiology equipment, catheter and heart and could result in lethal arrhythmias.
- To prevent injury to patient or operator, use extreme caution if employing components with unprotected male pin connectors during device set-up.
- Verify that all amplifiers, pacing equipment and ECG equipment is isolated or patient injury or death may occur. Recommended maximum leakage current from any connected device to the patient must not exceed 10 microamps.

Precautions
- Do not immerse cable connectors in liquids.
- Do not expose cables to strong solvents.
- Use of additional electrical equipment could cause noise induction into the cable.
- Follow standard grounding precautions for electrosurgical instruments.
- Prior to use, verify compatibility of electrophysiology catheter cable model with electrophysiology catheter model in use.
- Improper handling may result in patient or operator injury.

Adverse Reactions
None.

Directions for Use
1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify compatibility of all devices and accessories.
3. Inspect packaging before opening. The contents of the package are sterile if the package has not been compromised. Do not use the device if the sterility has been compromised. If the package is damaged or if it was opened and the device not used, return the device and package to Ascent Healthcare Solutions.
4. Do not attempt to resterilize.
5. Remove the device from the package and place it in a sterile work area using aseptic technique.
6. Inspect the device for overall condition and physical integrity. Do not use the device if any damage is noted. Return the device and packaging to Ascent Healthcare Solutions if it is not in acceptable condition for the procedure.
7. To attach the electrophysiology catheter cable to the electrode catheter, push the cable connector into the catheter connector. In models with arrow(s) on the cable connector, line up arrow(s) and line prior to pushing in.
8. Hold the catheter connector in place and push the extension cable connector firmly into the catheter connector.
9. Attach the electrophysiology catheter cable to the ECG monitoring or stimulation terminal.
10. Observe polarity of proximally located connector pins of the patient cable when connecting to the electrical equipment. Isolate any unused connector pins to reduce development of accidental current pathways to the heart.
11. If the electrode catheter needs to be repositioned, the electrophysiology catheter cable may be disconnected as the electrode catheter is moved to the new location under fluoroscopic guidance and reconnected. Verify proper catheter placement after relocation.

12. To disconnect, grasp the connectors on both cable and catheter side and pull. Do not pull directly on the cable or the catheter.
13. Follow a suitable electrophysiology study protocol.

Compatibility

- Use the appropriate reprocessed electrophysiology catheter cable for the electrode catheter being utilized.
- The connector on the proximal end is designed to universally fit electrophysiology recording equipment.

Storage and Handling

- Store at 10° C to 50° C.
- Do not expose to relative humidity above 95%.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.

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